REMARKS

In the Office Action dated July 21, 2009, claim 22 was examined while claims 1-21 and 23-39 remain withdrawn from further consideration in view of Applicant's previous election in response to the Restriction Requirement of August 25, 2006. The Examiner rejected claim 22, and made the rejection non-final. In response, Applicant has the following comments, and in view thereof, respectfully requests reconsideration of pending claim 22.

In the Office Action, claim 22 was rejected under 35 U.S.C. §102(b) as being anticipated by DeLuca et al US 5,843,928. The Examiner indicates that the '928 reference claims a novel class of 2-alkylidene-19-nor-vitamin D compounds (see claim 1), and claim 8 sets forth a specific side chain which is identical to the side chain of the vitamin D compound of present claim 22. Further, the Examiner states that the presently claimed compound of claim 22 is exemplified in claim 8 of the '928 reference when Y_1, Y_2, R_6 and R_8 are all hydrogen. The Examiner alleges that the compound of instant claim 22 is anticipated by the '928 reference because one of ordinary skill in the art would be able to "at once envisage" the specific compound of instant claim 22 within the generic chemical formula since the subgenus is more limited than the broad generic formula of claim 1 with the result that "very few combinations can be obtained." Thus, because of the limited genus set forth in claim 8 of the '928 reference, the Examiner alleges that one of ordinary skill in the art would "at once envisage" Applicant's claimed compound of claim 22 by selecting hydrogen for the various substituents Y_1, Y_2, R_6 and R_8 from the list of alternatives given in claim 8 of the '928 reference. Applicant, however, respectfully disagrees for the following reasons.

While it true that the compound of present claim 22 is encompassed by a combination of claims 1 and 8 of the '928 reference as stated by the Examiner, it is just as true that the compound of present claim 22 is not specifically disclosed in the '928 reference. The compound of present claim 22 is neither named nor specifically illustrated via a chemical structure in the '928 reference. This is, of course, important because, as the Examiner notes, a genus does not always anticipate a claim to a species within the genus unless the species is

clearly named and/or illustrated in the reference. When the compound is not specifically named, but instead it is necessary to select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific compound, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated so that one of ordinary skill in the art is able to "at once envisage" a specific compound within the generic chemical formula. Under the present circumstances, it is clear that the compound of claim 22 is not specifically named or illustrated in the '928 reference. Further, although the Examiner believes one of ordinary skill in the art is able to "at once envisage" the specific compound of claim 22, Applicant respectfully disagrees for the following reasons.

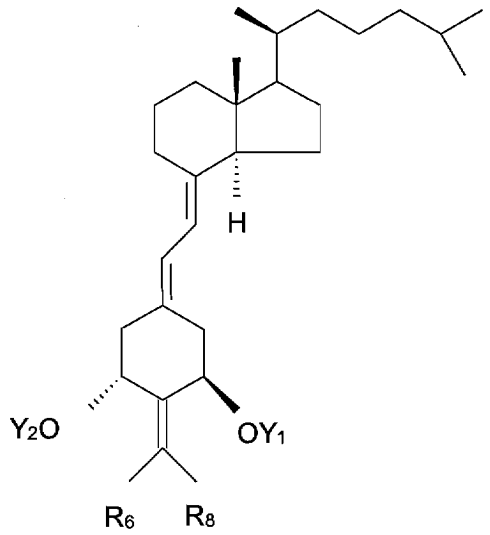
The Examiner cites the case of In re Petering, 133 USPQ 275(CCPA 1962) for support for the conclusion that the compound of present claim 22 is anticipated. In the case of In re Petering, the prior art disclosed a generic chemical formula which encompassed a vast number of compounds, and the court held that this formula, without more, could not anticipate a claim to a specific compound encompassed thereby. However, the court also concluded that the prior art disclosed preferred substituents which defined a sub-genus having a more limited generic class consisting of about 20 compounds. The court concluded that this limited number of compounds covered by the preferred formula in combination with other factors resulted in a finding that the reference specifically described each of the 20 compounds covered by the sub-genus formula. Since the claimed compound was one of those 20 sub-genus compounds, the court concluded that the claimed compound was anticipated by the description of the limited generic class covering those 20 compounds. The Examiner should note, however, that the present circumstances are significantly different than those found in the case of In re Petering.

With regard to the size of the sub-genus, the Examiner has combined claim 8 with claim 1 and concluded that the sub-genus is limited and thus "very few combinations can be obtained." For the convenience of the Examiner, Applicant has herein combined the side

chain of claim 8 with the generic formula of claim 1, and illustrates the structure of the combination below:

Combination of Claims 1 and 8 of the '928 References

A compound having the formula:



where Y_1 and Y_2, which may be the same or different, are each selected from the group consisting of hydrogen and a hydroxy-protecting group, R_6 and R_8, which may be the same or different, are each selected from hydrogen, alkyl, hydroxyalkyl and fluoroalkyl, or, when taken together represent the group—$(CH_2)_x$—where x is an integer from 2 to 5.

Although the side chain R has now been defined, the substituents Y_1, Y_2, R_6 and R_8 are still defined by the various definitions set forth in claim 1. Accordingly, the following alternatives are available for substituents Y_1, Y_2, R_6 and R_8:

(a) Y_1 may be selected from the group consisting of hydrogen and a hydroxy-protecting group. A hydroxy-protecting group is defined at column 5, line 64 through

column 6, line 21 as alkoxycarbonyl, acyl, alkylsilyl, alkylarylsilyl and alkoxyalkyl groups. Alkoxycarbonyl-protecting groups are defined as alkyl-O-CO-groupings with at least 9 specific example compounds listed. The term "acyl" is defined as an alkanoyl group of one 1 to 6 carbons in all isomeric forms or a carboxyalkanoyl group of 1-6 carbons or an aromatic acyl group. The word "alkyl" is defined as a straight or branched alkyl radical of 1 to 10 carbon atoms in all isomeric forms. At least 5 different alkoxyalkyl groups are then defined as are 7 different silyl-protecting groups. Finally, the term "aryl" is defined as a phenyl-, or an alkyl-, nitro- or halo- substituted phenyl group. As the Examiner can see, the definition of Y_1 encompasses a vast number of alternative compounds.

(b) Y_2 in the above formula is also defined as being selected from hydrogen and a hydroxy-protecting group. A hydroxy-protecting group is defined at column 5, line 64 through column 6, line 21 wherein a hydroxy-protecting group is defined as alkoxycarbonyl, acyl, alkylsilyl, alkylarylsilyl and alkoxyalkyl groups. Alkoxycarbonyl-protecting groups are defined as alkyl-O-CO-groupings with at least 9 different example compounds listed. The term "acyl" is defined as an alkanoyl group of one 1 to 6 carbons in all isomeric forms or a carboxyalkanoyl group of 1-6 carbons or an aromatic acyl group. The word "alkyl" is defined as a straight or branched alkyl radical of 1 to 10 carbon atoms in all isomeric forms. At least 5 different alkoxyalkyl groups are then defined as are 7 different silyl-protecting groups. Finally, the term "aryl" is defined as a phenyl-, or an alkyl-, nitro- or halo- substituted phenyl group. As the Examiner can see, the definition of Y_2 encompasses a vast number of alternative compounds.

(c) R_6 in the above sub-genus formula is selected from hydrogen, alkyl, hydroxyalkyl and fluoroalkyl, or when taken together with R_8 may represent the group –$(CH_2)_x$—where x is an integer from 2 to 5. The term "alkyl" is defined at column 6, lines 10-13 as a straight chain or branched alkyl radical of 1 to 10 carbons, in all of its isomeric forms. The term "hydroxyalkyl" is defined at column 6, lines 26-29 as being an alkyl

radical substituted by one or more hydroxy groups. The term "fluoroalkyl" is defined at column 6, lines 26-29 as being an alkyl radical substituted by one or more fluoro groups. The Examiner should remember that the term "alkyl" is defined as having 1 to 10 carbon atoms and may be straight and/or branched in all isomeric forms. Thus, once again, the definition of R_6 encompasses a vast number of compounds.

(d) R_8 in the sub-genus formula noted above may also be selected from hydrogen, alkyl, hydroxyalkyl and fluoroalkyl or when taken together with R_6 may represent the group $-(CH_2)_x-$—where x is an integer from 2 to 5. The term "alkyl" is defined at column 6, lines 10-13 as a straight chain or branched alkyl radical of 1 to 10 carbons, in all of its isomeric forms. The term "hydroxyalkyl" is defined at column 6, lines 26-29 as being an alkyl radical substituted by one or more hydroxy groups. The term "fluoroalkyl" is defined at column 6, lines 26-29 as being an alkyl radical substituted by one or more fluoro groups. The Examiner should again remember that the term "alkyl" is defined as having 1 to 10 carbon atoms and may be straight and/or branched in all isomeric forms. Thus, once again, the definition of R_8 encompasses a vast number of compounds.

Applicant is not quite sure how many different combinations are defined by the above sub-genus formula in view of the definitions for Y_1, Y_2, R_6 and R_8, but it is clear that the sub-genus formula representing a combination of claims 1 and 8 of the '928 reference encompasses a vast number of compounds, and clearly encompasses a number which is very significantly greater than the 20 compounds set forth in the case of In re Petering. Thus, the present situation is clearly distinguishable over In re Petering especially when one considers the large size of the sub-genus combination of claims 8 and 1 of the '928 reference.

The Examiner also notes that "one may look to the preferred embodiments to determine which compounds can be anticipated." The Examiner apparently is considering the side chain of claim 8 to be a "preferred" embodiment. However, nowhere

in the description of the '928 reference does it state that the side chain defined by claim 8 is a "preferred" side chain. What is stated in the '928 reference can be found at column 3, lines 45 through column 4, line 5 which states:

> "Specific important examples of side chains with natural 20R-configuration are the structures represented by formulas (a) (b), (c), (d) and (e) below..." (emphasis added)

The Examiner will note, however, that the specific important examples of side chains illustrated contain the 20(R) configuration, i.e. the methyl group attached at the 20 carbon position of the side chain is in its natural or R-configuration which is represented by the dashed lines extending from the 20 carbon position. In contrast, the compound being claimed in instant claim 22 has the methyl group at carbon 20 in its S-configuration. This is represented by the solid wedge-shaped bond extending from carbon 20 rather than the R-configuration represented by the dashed lines noted above. Thus, nowhere in the '928 reference does it state that the 20(S) configuration is "preferred" as alleged by the Examiner. The fact that the '928 reference refers to the 20(R) configuration as "important" examples of side chains, but does not state the same with respect to the 20(S) configuration, weighs against selecting the 20(S) claimed species or sub-genus by one skilled in the art. It appears that one skilled in the art would first select the 20(R) configuration rather than the 20(S) configuration as alleged by the Examiner.

In summary, the mere fact that a combination of the structures shown in claims 8 and 1 of the '928 reference teaches a smaller genus than that of claim 1 alone, does not mean that the compound of claim 22 is anticipated thereby. As described above, a combination of claims 8 and 1 still describe a genus which encompasses a vast number of compounds. In addition, there is no teaching or suggestion in the '928 reference to one skilled in the art to select the claimed compound of instant claim 22. Instead, the disclosure of the '928 reference seems to teach away from selecting a compound having

the 20(S) configuration. Accordingly, Applicant requests the Examiner withdraw the rejection of claim 22 under 35 U.S.C. §102(b) based upon the '928 reference.

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

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